

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
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4 IN RE OCULAR THERAPEUTIX, INC.)
5 SECURITIES LITIGATION,) No. 17-CV-12288-GAO
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9 BEFORE THE HONORABLE GEORGE A. O'TOOLE, JR.
10 UNITED STATES DISTRICT JUDGE
11 MOTION HEARING
12
13

14 John Joseph Moakley United States Courthouse
15 Courtroom No. 22
16 One Courthouse Way
17 Boston, Massachusetts 02210
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21 February 6, 2019
22 2:00 p.m.
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P R O C E E D I N G S

THE CLERK: All rise.

(Court enters.)

THE CLERK: Court is now in session on the matter of
In Re Ocular Therapeutix litigation, Civil Action 17-CV-12288.

Counsel, please identify yourselves for the record.

MR. VAN: Austin Van on behalf of lead plaintiffs, and
with me are Joseph Cohen from Glancy Prongay & Murray, he's
co-lead counsel, and Daryl Andrews, who is liaison counsel.

THE COURT: Good afternoon.

MR. BONGIORNO: Good afternoon, your Honor. On behalf
of all defendants, from Wilmer Hale, Mike Bongiorno, Peter
Kolovos, Joseph Yu and Katherine Mackey.

THE COURT: Okay. Defendant's motion.

MR. BONGIORNO: Thank you, your Honor.

THE COURT: Good afternoon again.

MR. BONGIORNO: As I mentioned, I represent all of the
defendants in this case, but there are only, I guess, three
active defendants for this motion because the plaintiffs
concede, right at the beginning on page 1 of their opposition
to our motion, that they are not contesting the motion to
dismiss as it relates to George Migauskys and Eric Hurley. So
we're -- Andrew Hurley, I apologize. So we're left with Amar
Sawhney, Eric Ankerud and the corporate defendant Ocular. And
those three defendants should be dismissed, just like the other

1 two were dismissed, your Honor, because this is another
2 textbook example of fraud by hindsight based on a company, like
3 others we've seen before, that is going through an FDA process
4 and dealing with their regulator, and the back and forth with
5 the regulator ultimately hits a few bumps in the road. Those
6 are disclosed as they happen, the stock price goes down, the
7 market reacts, but yet at the end of the narrative, when the
8 stock price settles, wherever it settles, we see a lawsuit.

9 In fact, we saw the lawsuit before the end of the
10 class period. I think the lawsuit was filed in early July, and
11 it wasn't for another couple of days that the rest of the air
12 had been taken out of the stock, and ultimately when the
13 definitive complaint was filed, it was filed with a class
14 period that ends after the first complaint was filed. So they
15 were pretty anxious to pursue this case, but it's not much of a
16 case when you get down to it.

17 It's really just another case about some disappointing
18 results from the back and forth with the FDA regarding some
19 manufacturing issues that they observed and had caused the FDA
20 to issue a complete review letter in response to the original
21 new drug application, and then another complete review letter
22 in response to the resubmitted new drug application that
23 resulted in delays in getting this product ultimately approved.

24 Of course in the meantime, there were inspections of
25 the manufacturing facilities up here in Bedford, and those

1 inspections resulted in 483s being issued. I know the court's
2 familiar with what those are from the *Genzyme* case, but those
3 are non-final, non-definitive observations that the FDA makes
4 when it visits a manufacturing facility for one of its
5 regulated companies.

6 You know, here the Form 483s were issued. The company
7 disclosed them. The company submitted new drug applications.
8 The FDA came back within the PDUFA deadlines that are set by
9 statute for responding to a new drug application. They issued
10 a complete review letter. The complete letter says the drug
11 isn't approved at this time.

12 They resubmit. There's another inspection. There's
13 another 483. That's disclosed. The NDA is considered, the
14 PDUFA deadline comes. The FDA again says, can't approve it
15 this time. Fortunately the drug was ultimately approved last
16 year. So these issues were overcome, but in the meantime these
17 bumps in the road caused some hits in the stock price and
18 ultimately this lawsuit.

19 But this lawsuit is different from other lawsuits,
20 even ones that didn't survive. It's easily distinguishable
21 from the ones that did. It's also an even weaker case than
22 some of them that didn't, including the one I mentioned before,
23 the *Genzyme* case, which this court decided and was confirmed by
24 the First Circuit, of course. In that case, the 483s were not
25 disclosed immediately. They weren't disclosed until later,

1 when other things happened, like a warning letter.

2 Here, in both instances, the 483s were disclosed.
3 It's a strange case. Right? The class period starts the day
4 the company discloses the 483. And what's the theory? The
5 theory is that the company said that it complied with cGMP,
6 good manufacturing practices. And the theory is, well, that
7 has to be false or misleading because the company had a 483
8 letter that observed these violations of FDA protocols.

9 Well, we know two things, right? We know, number one,
10 it's not a definitive conclusion of anything. It's just an
11 observation that the company has an opportunity to respond to.
12 We also know, number two, that it was disclosed publicly. So
13 whatever you can take from the fact that the company got a 483
14 letter from the FDA, it's publicly known.

15 So if the plaintiffs are right, as they say in their
16 complaint, that the existence of a Form 483 shows -- what did
17 they say -- strongly indicates to investors that the company is
18 not in compliance with cGMP -- I don't think that's what it
19 says or what it actually indicates, but if they're right about
20 that, the public knows about it, because they disclosed the
21 existence of it. So if it is such a strong indication of
22 violations of cGMP, then the public knows about that, and the
23 statement, the sort of generic one sentence in a 120-page 10-K
24 that says we complied with the cGMP but the market is not going
25 to take anything from that relative to the Form 483, which is

1 the only thing they have.

2 I know that in *Genzyme* -- I'm sorry.

3 THE COURT: Are you saying that a statement that is so
4 bald-facedly wrong that the public understands it to be untrue
5 is not an actionable statement?

6 MR. BONGIORNO: Well, I certainly wouldn't put it that
7 way, your Honor, but I understand what you're saying.

8 THE COURT: I wouldn't think you would.

9 MR. BONGIORNO: I don't think it's so obviously wrong
10 in any respect.

11 What I am saying is, because I don't buy for one
12 second the plaintiffs' notion that the existence of a 483 so
13 strongly indicates violations of cGMP, what I am saying is if
14 you take them at their word that that's what it means, it's all
15 in one paragraph. The paragraph about the 483 starts in the
16 10-K with, We are regulated by the FDA. The FDA enforces its
17 rules and regulations. The FDA makes sure the companies are in
18 compliance with cGMP. It says, actually cGMP in the paragraph
19 about the 483. It says they come and they inspect. They
20 inspected last year. They issued a Form 483. We resolved it.
21 Then they came this year and issued another one, and we're
22 trying to resolve that one. But if we don't, it could delay
23 the approval. It could delay the application. It could delay
24 the approval of the application. It could result in fines,
25 penalties, suspensions.

1 It's all right there for the reader, so the reader can
2 understand what's going on at the company. The company has a
3 product at the time, by the way, that it is manufacturing and
4 selling. DEXTENZA was not its only product. So obviously the
5 company is manufacturing things in accordance with cGMP or the
6 FDA would have put a stop to the manufacture or sale of the
7 earlier product.

8 The point is they came in and they observed some
9 things that they viewed as irregular that they think the
10 company should deal with and address, and the company discloses
11 right up front. We just got this, and we're trying to address
12 it. But if we can't address it, then it's going to be a
13 problem with our application, with the approval process, and
14 could result in delays. I'm not sure what else they were
15 supposed to say.

16 Genzyme had basically the same disclosure in its 10-K
17 about cGMP, and that's in the complaint in the *Genzyme* case.
18 And in *Genzyme* they don't even disclose the 483 until months
19 later. But the court was absolutely right, and you obviously
20 don't need me to tell you that. The First Circuit said so.

21 THE COURT: And I believe them when they say that.

22 MR. BONGIORNO: I do too, your Honor.

23 THE COURT: I don't always believe them.

24 MR. BONGIORNO: Right. Your Honor, I do especially in
25 this case.

1 THE COURT: Let me clarify one point.

2 MR. BONGIORNO: Sure.

3 THE COURT: DEXTENZA was used for two applications, or
4 was intended for two applications, I understand. One was for
5 pain relief. One was for something else. One was in Phase II
6 and one was in Phase III. Does that make any difference?

7 MR. BONGIORNO: I don't think so.

8 THE COURT: It's the same drug, so it doesn't matter?

9 MR. BONGIORNO: Yes.

10 THE COURT: Okay.

11 MR. BONGIORNO: And it's inserted into the eye --

12 THE COURT: Right.

13 MR. BONGIORNO: -- to release the drug to avoid, you
14 know, patients post surgery having to put in eye drops, which
15 they're not going to necessarily do exactly the way they're
16 supposed to do. It's a lot harder to do. An implant is
17 obviously a serious surgical procedure, but once it's done, the
18 drug is released from the implant in the eye, and that's it,
19 and it deals with inflammation, and it deals with irritation in
20 the eye, pain in the eye. So it does have those two
21 indications. It's called a plug for what that's worth. It
22 doesn't sound very pleasant to me, but apparently is a good
23 thing for folks who are suffering from that particular issue.

24 So just to go on to what the statements are that we're
25 dealing with. We already touched on the first one, your Honor,

1 regarding the compliance with cGMP. Again, I think that it's a
2 tough case to make out that that's a false and misleading
3 statement when in the same document and, indeed, in a paragraph
4 that discusses cGMP, the company's discussing exactly what is
5 going on with the 483.

6 Now, I don't concede for one second that the company
7 wasn't complying with cGMP. My only point is that even if they
8 weren't, or even if those FDA observations, which are not
9 final, ultimately ended up being part of what the FDA decided
10 when they issued the CRL, at that point in time, A, they're not
11 final, they're just observations. So there's no reason for the
12 company to change what it's saying. And, number two, the
13 information is out there anyway. It's in the same document.
14 It's in the same paragraph. It's hard to make an omissions
15 case out of something that was supposedly withheld from the
16 market when it's in the very same document from which it's
17 supposedly omitted. So that information is there.

18 So all they're left with is, well, the 483 is worse
19 than you said. It was really bad. It wasn't just kind of bad.
20 It was really bad. And the case law doesn't support any notion
21 like that. The company doesn't need to say, and there's no
22 basis for them to have said, you know, this is a massive
23 problem that requires a complete overhaul of our manufacturing
24 processes, which is what they say we should have said. There's
25 no basis for that. There's no confidential witness that says

1 anything like that. There's no internal document that says
2 anything like that. There's not even an allegation that that's
3 actually what had to happened. It's just their blanket
4 statement of hyperbole that this was so bad that the drug could
5 never be approved and the manufacturing process could never be
6 fixed.

7 Of course, ultimately it was fixed and the drug was
8 approved, but that's beside the point. I understand that we're
9 viewing this contemporaneously with when things were said. And
10 I don't want to say that we get truth by hindsight any better
11 than they get fraud by hindsight, but they don't get fraud by
12 hindsight here. It has to be what did they know at the time.
13 We haven't even gotten some answers yet.

14 But what are the facts? I mean, the facts are they
15 got a 483. They disclosed it. They tried to respond to it as
16 best they could. They gave general statements of optimism
17 surrounding it. That was before this court, the *ConformIS*
18 case. And in that case this court held that those types of
19 statements, like we have here, "we think," "we believe," are
20 just blanket statements of opinion. Not only are they
21 forward-looking, they're statements of opinions. And for both
22 of those reasons, those type of statements aren't actionable.

23 So the statements that we have in the conference
24 calls, that the two defendants, active defendants, namely
25 Dr. Sawhney and Mr. Ankerud, about, We think we'll be able to

1 address this, we believe we're on track and will be able to
2 respond in a timely matter, those aren't actionable for the
3 simple pure reason that they are forwarding-looking, they are
4 statements of opinion. So there's no basis to say that they
5 were fraudulent when they were made.

6 Getting to the scienter point on those statements,
7 again, we have nothing, nothing to show that the plaintiffs
8 didn't believe -- or that the defendants didn't believe what
9 they were saying when they said it, that it wasn't reasonable
10 for them to think that they could overcome these things in a
11 timely manner. All we have is they didn't overcome them in a
12 timely manner, therefore, they weren't true when they said
13 them, and not only that, the defendants didn't think they were
14 true.

15 Then they tried to turn scienter right on its head
16 because we have no sales of stock during the class period. We
17 have a large purchase of stock during the class period by
18 Dr. Sawhney. And that's over 50,000 shares that he bought
19 during the class period, more shares than three out of the four
20 the lead plaintiffs bought during the class period. But
21 somehow when the defendants buy that many shares, that's not a
22 lot of shares. 50,000 shares is a lot of shares. And they
23 say, well, not for Dr. Sawhney, it's not, because he owned tons
24 of other shares. Okay. What does that tell you? That he had
25 a huge amount of shares that he could have sold if he thought

1 the stock price was inflated, but not only did he not sell any
2 of them, he bought some.

3 Then they say look at the *ModusLink* case, Judge. In
4 that case the court -- I think it was Judge Casper -- said,
5 Well, maybe if you're buying stock it's because you're trying
6 to hide something, whatever, and they say you can take that
7 inference. The *Abiomed* case from the First Circuit from 2015
8 disposes of that notion.

9 Accumulated stock during the class period weighs
10 against motive and, therefore, against scienter, not for it.
11 So you don't have anything resembling a feather on the scale
12 for scienter, but you have this against it, and you also have
13 the very reasonable -- reasonable inference here that these are
14 folks who were trying to address this problem.

15 They got a letter from the FDA, that the plaintiffs
16 don't dispute, that said with regard to the first 483, there
17 was a press release after that 483 came that the company issued
18 that said, We're responding to it. We've submitted our plan,
19 and the FDA's agreed with our plan for dealing with nine out of
20 the ten observations from the first 483.

21 So the reasonable inference is that here you have a
22 company that's making progress with the FDA, disclosing
23 everything as it happens. You get a 483, you disclose it;
24 submitted an NDA, got a CRL within the PDUFA date, disclosed
25 that. Resubmitted an NDA, disclosed that. Got another 483

1 from the second inspection, disclosed that. Got a CRL in
2 response to that second NDA, disclosed that.

3 So the back and forth and the cadence with the FDA is
4 typical. It's not perfect. It's not what the shareholders
5 hoped for. It's not what the company hoped for, but it's not
6 unusual and it was all disclosed from start to finish.

7 The only thing left to disclose is how bad it was.
8 Look how bad this 483 was. Look how bad that 483 was. Again,
9 I go back to the *Genzyme* case, and all the different cases
10 cited in it in the First Circuit that say you don't even have
11 to disclose a 483. Maybe there are some circumstances where
12 you do, I suppose. But in that case you had 483s that weren't
13 even disclosed, and there was no claim stated. I mean, you
14 have some of these cases where people are getting indicted and
15 there are criminal complaints and other things going on. Here
16 there's nothing like that. All you have -- they try to throw
17 an SEC investigation that has led to nothing to date onto the
18 scale in favor of scienter. That doesn't work. An SEC
19 investigation doesn't equate to scienter. All you have are
20 interim disclosures along the way, public statements about
21 what's happening, the stock price going down and, again, the
22 class period that started with a disclosure that the company
23 got an observational letter from the FDA, a 483, saying here
24 are some issues with your manufacturing.

25 Now, the other thing they're going to say undoubtedly

1 is, because it's in their papers, is, well, the second 483
2 shows that they never fixed anything from the first 483, and it
3 was going on the whole time and, therefore, it's unreasonable
4 to say that they were making progress and these forward-looking
5 statements and these statements of opinion had no reasonable
6 basis because they were never in compliance because they never
7 fixed anything. Well, first of all, a comparison of the two
8 483 letters shows that that's not true.

9 Second of all, again, that's fraud by hindsight.
10 That's, you said you thought you could fix the issues in the
11 first 483, but you were lying; and do you know how we know you
12 were lying? Because you didn't fix them.

13 That's not a securities fraud case. That's a failure
14 to get to the point you're trying to get to. That's a failure
15 to get to the end zone when you're on your way or you hope
16 you're on your way and you think you're on your way. But it's
17 not even true in the first place because the second 483 makes a
18 point that I hate saying because I can never pronounce it, a
19 particulate matter is what it says, that there's a particulate
20 matter, a foreign substance, in the plug or in the drug,
21 whatever, the product that's being produced.

22 In the complaint they try to say, look at that, that's
23 a bombshell disclosure. I don't know if it's a bombshell
24 disclosure or not, I don't think so, but it's our disclosure.
25 We said it. It's in the 483. But it's not in the first 483.

1 If you read the complaint and you read the opposition to the
2 motion to dismiss, you would think it is in the first 483, but
3 it's not. They try to extrapolate that it must have been part
4 of the same issue and the same problem or whatever, but it's
5 not. The FDA doesn't say it until the second one. So this
6 notion that there's this one long lingering problem that we
7 keep trying to gloss over and say isn't a problem is just not
8 true. It doesn't hold out.

9 So we don't have a false or misleading statement. We
10 don't have an omission, because the thing that they say was
11 omitted that caused the statement to be false and misleading
12 was actually said, unlike the case law that is already in our
13 favor. We actually go one better by disclosing it. So we
14 don't have a false and misleading statement. We don't have an
15 omission. And we certainly don't have scienter.

16 For all of those reasons, your Honor, I would ask that
17 this court dismiss this case and that it do so with prejudice,
18 like it's done in *ConforMIS*, like it's done in *Genzyme*, and
19 there's no reason to think that this case is any different or
20 would look any different if they were allowed to amend.

21 If the court doesn't have any questions, I will --

22 THE COURT: Thank you.

23 MR. BONGIORNO: Thank you.

24 MR. VAN: So lead plaintiffs respect what Ocular is
25 doing. They're trying to develop a drug for post-surgical

1 pain. No doubt that was one of the reasons that lead
2 plaintiffs purchased their stock. It's an admirable goal. But
3 it has to be said that during the class period Ocular was a
4 completely inept drug manufacturer. There are two general ways
5 in which this company didn't have its act together in
6 manufacturing drugs. Many more than that, but I think that
7 most of these observations can be described in two sets.

8 The first is that the company didn't have a recipe for
9 making their drug. The company didn't know how to make
10 DEXTENZA. They hadn't figured it out yet. They were not able
11 consistently to make their drug product. They weren't able to
12 make a drug that had the strength and quality and purity that
13 they claimed it had. They weren't able to make this drug.

14 The second is that there was stuff in the drug that
15 they didn't know what it was. There was unidentified stuff in
16 this drug throughout the class period. That's a huge problem.
17 You can't be putting a drug out into the market that has some
18 unidentified stuff in it that, incidentally, turned out to be
19 aluminum, a heavy metal, toxic to humans, and expect the FDA to
20 approve your drug. There is no -- anyone sitting in this
21 courtroom recognizes that if, A, you don't have a recipe for
22 your drug, you haven't figured out how to make it, and, B, you
23 have stuff floating around in your drug and you don't know what
24 it is, it might be toxic, the FDA isn't going to let your drug
25 go forward. It's not going to say it's compliant with current

1 good manufacturing practices. Any old fool would know that.
2 Defendant Ankerud and the person to whom he reported, Sawhney,
3 aren't any old fool. They had a lot of experience in this area
4 and they certainly knew it.

5 So there are only two elements at issue here that
6 they're disputing with respect to this Section 10(b) claim,
7 falsity and scienter.

8 Falsity really should not be in dispute, at least with
9 respect to the cGMP compliance statements, because the FDA in
10 these complete response letters that were issued twice during
11 the class period said we have determined that your operations
12 are not compliant with cGMP for the reasons that we offered in
13 our February Form 483s. It's been determined. The government
14 agency responsible for making this determination has said you
15 weren't compliant. So falsity, was it a true or false
16 statement, we are cGMP compliant? No, it shouldn't be a
17 question.

18 All the defendants say on this is nothing to do with
19 falsity. Their response goes to scienter, but we're not
20 talking about scienter at the moment. We're talking about
21 falsity. Falsity should not be at issue here because the
22 government has made a determination of falsity.

23 Scienter is just as clear, and, frankly, we don't even
24 need these complete response letters to show falsity. Falsity
25 is also totally clear, as is scienter, from the observations

1 made by these inspectors that went into the facility and looked
2 around and made descriptions. They described the conditions of
3 the manufacturing operations. And we plead those, and this
4 court has to accept our well-pleaded allegations of those
5 descriptions of the manufacturing operations as true. So they
6 are true. And as we've gone through before, those -- the gist
7 of those observations were that the company didn't have a
8 recipe and it had stuff floating around in its product. And it
9 should be clear to everyone, certainly including defendants,
10 both the statement of false -- the falsity is clear from those
11 observations because they're not cGMP compliant if there's no
12 recipe and there's stuff floating, and they should have known
13 they weren't cGMP compliant if they didn't have a recipe and
14 there was stuff floating around in their product.

15 So let's go through the four misstatements -- well,
16 four dates of misstatements and get a little more specific.

17 So the first false and misleading statement is in the
18 March 2016 Form 10-K, and that is the first time the company
19 comes out and says, We are cGMP compliant. Of course they
20 weren't. They had received a Form 483 detailing the
21 inspectional observations made by the inspector in February of
22 2016.

23 Now, defendants throw up their arms and say it's not
24 the case, as this court correctly held, by the way, in *In Re*
25 *Genzyme*, it's not the case that just because the company

1 receives a Form 483 that the company should know that it's not
2 cGMP compliant. That does not follow. We absolutely agree
3 with your Honor on this point and with defendants. It says on
4 the Form 483 this is an interim observation. We're not
5 claiming to the contrary.

6 The only relevance of the Form 483 is it's the same
7 relevance they would have if they were made by a third-party
8 inspector who wandered into the operations and faithfully wrote
9 down descriptions of what he saw, said these are what the
10 operations are like. Those descriptions are pleaded with great
11 specificity, and the court has to accept them as true. That's
12 the only purpose of the Forms 483. And it follows from those
13 observations that -- it's just obvious that the company wasn't
14 compliant with cGMP because they didn't have a recipe and there
15 was stuff floating around in their product. And they knew that
16 much because everybody in this room knows that.

17 Okay. In the reply defendants say, well, there is
18 this case which said that if the company receives a Form 483,
19 then that's not sufficient to show that the company knew that
20 it wasn't cGMP compliant. So it's also -- it must be the case,
21 it follows that the observations made in the Form 483 aren't
22 sufficient to show that a company isn't cGMP compliant. Non
23 sequitur. The observations, just as in this case, absolutely
24 are sufficient. The observations are just descriptions of what
25 was going on in the facility, and from those observations it's

1 clear that the company did not have -- was not close to having
2 its act together in the manufacturing of this drug. It didn't
3 even know how to make it.

4 So the November 9 conference call. Here the company
5 states, We've adequately, we think, addressed the issues that
6 they have raised. Now defendants say, Well, this is puffery.
7 It's clearly not. This is a statement about compliance. We
8 think we've adequately addressed the issues is just to say we
9 think we're now compliant. We think we've adequately addressed
10 the issues. We think we're compliant with cGMP. And a
11 statement of belief in compliance is actionable under *Omnicare*.
12 It's actually the example that the Supreme Court gave in
13 *Omnicare* of an actionable statement of opinion.

14 And the standard under *Omnicare* for the actionability
15 of a statement of opinion is that the statement is actionable
16 if it does not fairly align with the information in the
17 speaker's possession at the time. Regardless of whether the
18 defendants believed -- were completely irrational and for some
19 reason thought that their operations, when they didn't have a
20 recipe and there was stuff floating around in their product,
21 that they didn't know what it was, was cGMP compliant, even if
22 they irrationally believed that, the information in their
23 possession at the time, which was a list of these things, a
24 list of ways in which they were not cGMP compliant, a list of
25 the problems, a description of their facilities, did not fairly

1 align with that belief. This description saying, well, you
2 don't have a recipe, did not fairly align with their statement
3 we are cGMP compliant. So this opinion, we've adequately
4 addressed the issues, is actionable, just as any other
5 statement of belief in compliance would be actionable.

6 So defendants say, well, there are no contemporaneous
7 facts showing that as of November 9 or November 2016 the
8 company wasn't cGMP compliant. So that's certainly not the
9 case. These problems were continuing. So there's two problems
10 that I put forward: No recipe and stuff floating around in the
11 product were in both inspectional observations, and I can go
12 through and show you that.

13 In the first, February 11, 2016, Observation 3 is that
14 they didn't have procedures. Procedures were not established
15 to monitor outputs and validate manufacturing processes
16 responsible for causing variability in the in-process material
17 and the drug product. And they specified that what was really
18 going on here was that the company hadn't figured out a way to
19 mix the product together in such a way that the bulk
20 preparation of the product was consistent throughout. And that
21 can be tricky. It can take years. In fact, in this case it
22 did take years. They didn't know how to make their product,
23 and that is clear from Observation 3. That's what it's saying.
24 And we consulted an expert at length and went through all these
25 observations and that's what the expert told us. Okay.

1 And then as for stuff floating around, Observation 1
2 notes that there was a regularly occurring impurity.

3 Observation 6 says that the control didn't include
4 procedures designed to assure purity. Observations 7 and 8
5 note that the company didn't even have the right equipment to
6 assure that there was no product contamination or micro-
7 organism growth.

8 So both of these concerns were clearly present in the
9 first Form 483, and they remained in the second Form 483. As
10 for, We don't know how to make the product, Observation 3 says,
11 "There are no written procedures for production and process
12 controls designed to assure that the drug products have the
13 identity, strength, quality, purity they purport or are
14 represented to possess." No recipe.

15 And as for the stuff floating around in the product,
16 well, that's front and center, Observation number 1. There was
17 unknown and uninvestigated particulate matter that had been
18 found in 10 of 23 of the lots they produced. What happened to
19 those other lots? They were scrapped before there was even a
20 visual inspection of them. That's how bad those lots were. Of
21 the 10 that survived, those had unknown particulate matter,
22 unknown and uninvestigated. The company wasn't even looking
23 into it before the FDA came along.

24 And what was that stuff? They noted that it was
25 aluminum, a heavy metal. That's bad stuff. You don't want to

1 be eating aluminum.

2 Observation 4 noted that the procedures for the
3 quality control unit were not in writing. That also goes to
4 purity.

5 Observation 5 noted that the laboratory controls were
6 not appropriate to assure purity. It also goes to stuff
7 floating around in the product.

8 So these two concerns were present throughout. So any
9 notion that at any point the company was cGMP compliant
10 suggests that maybe three days randomly and then this two-year
11 period the company happened to come across and have a recipe,
12 and it happened to eliminate all this free-floating stuff in
13 their product. But then three days later imagine that they
14 went back to being non-compliant. It's a ridiculous notion
15 that reasonable jurors would not accept.

16 THE COURT: I understand you've taken the position
17 that the fact of citation in a 483 establishes the fact
18 alleged.

19 MR. VAN: Yes, your Honor.

20 THE COURT: Without any further process?

21 MR. VAN: I'm not sure I understand the question.

22 THE COURT: Discussion, dialogue, none of that can
23 affect the factual certainty or the established fact --

24 MR. VAN: That's absolutely right. The FDA doesn't go
25 back and do a second inspection.

1 THE COURT: No, no. I just want -- you're saying when
2 the 483 says you don't have a procedure adequate to do this,
3 that that fact is then established.

4 MR. VAN: Yes. That observation is -- well, the legal
5 -- what is not established, what remains interim is the legal
6 conclusion drawn from those observations. And this is a
7 distinction that is critical.

8 THE COURT: Well, what I'm getting at, perhaps you can
9 foresee, is that the process itself seems to allow for some
10 back and forth between the company in response and the FDA in
11 response to the assertions in the 483. And apparently, it
12 seems to be the case in many cases, they work it out, which
13 means -- I guess, which is -- it means the facts change
14 somehow. So that's what --

15 MR. VAN: Right. So --

16 THE COURT: The assertion of it by a citator
17 establishes it, but it might change because it might be
18 resolved. So the violation goes away and the non-compliance
19 goes away, and so on and so forth. Isn't that the real world?

20 MR. VAN: They could change it. But it would still --
21 it would remain true that as of the date of the inspection, the
22 observations of their facilities and their manufacturing
23 processes were as they were. And this court can't challenge
24 those factual allegations. Those are well-pleaded factual
25 allegations that have to be accepted as true for the purposes

1 of the motion to dismiss. This is not the time for us to be
2 having --

3 THE COURT: It's certainly true they were stated, they
4 were cited. There's no question about that.

5 You're saying it establishes the historical fact of
6 the situation on the ground as it were.

7 MR. VAN: It absolutely does. All we need --

8 THE COURT: What's the point of an iterative process
9 with the company then that the FDA itself allows? The FDA
10 doesn't even take it as an established fact forever. Why
11 should anybody else?

12 MR. VAN: Well, this court --

13 THE COURT: Except by the time the complaint gets
14 filed.

15 MR. VAN: So I'm not sure your Honor is right. In
16 fact, respectfully, I think you're wrong. I think the FDA
17 doesn't say, well, those processes weren't -- the inspector was
18 hallucinating. The inspector didn't adequately describe what
19 was the conditions of the site.

20 THE COURT: No, they wouldn't say that. They would
21 just say, okay, after further investigation, and we understand
22 now, the company does this and has corrected this, and the
23 model has changed, and so on. Now we're satisfied. We
24 withdraw the objection. It's okay now. Isn't that what
25 happens sometimes?

1 MR. VAN: It's absolutely not what happened here. At
2 no point did the FDA say, Well, something changed and now those
3 observations that we made back in the day aren't accurate
4 somehow. At no point did that happen.

5 So we absolutely have a legitimate basis to plead that
6 the conditions of the facility were as they were described.
7 That's all we need, incidentally. We're not relying on any
8 legal conclusion. It could just as well not have been the FDA
9 that was doing these inspections. It could have been some
10 random third party who happened to know something about drug
11 manufacturing wandering in and looking around and writing down
12 in a journal what he saw. That would be a legitimate basis for
13 us to plead the conditions of the manufacturing facility as of
14 that date.

15 So certainly if the FDA's inspector, who he is a, you
16 know, a government inspector, a priori is a legitimate basis to
17 plead the conditions of the manufacturing facility.

18 THE COURT: Some of those things might be objectively
19 determinable. For example, the 483 might say the temperature
20 in the lab was 96 degrees Fahrenheit. That's way too high.
21 Okay? There might also be a judgmental component like how high
22 is way too high? A good bit of the FDA regulations on
23 manufacturing practices use words like "appropriate" and things
24 like that, involving some judgment.

25 And couldn't there be a reasonable scientific dispute

1 about whether something was a certain level, if something was
2 appropriate?

3 MR. VAN: Maybe at some point in this case we'll have
4 a factual dispute about whether or not the inspectors were
5 correct. That's certainly not the stage that we're at now when
6 we're simply pleading allegations, your Honor.

7 THE COURT: Right. So the initial citation of the 483
8 should be taken as fact, even though there might be some debate
9 about the correctness of subjective judgments?

10 MR. VAN: So I don't think -- so yes.

11 THE COURT: Okay.

12 MR. VAN: By the way, yes, absolutely. Your Honor is
13 required to accept --

14 THE COURT: That's what I had understood you to say,
15 and I just wanted to be sure I was understanding you.

16 MR. VAN: Right. But just to -- these concerns, like
17 you don't have a recipe, aren't -- they literally did not have
18 a written protocol, and the existence or non-existence of a
19 piece of paper is kind of like measuring the temperature. We
20 observed things floating around in your product is like looking
21 at the temperature. These are not subjective judgments. There
22 either are or are not things floating around in your product.
23 That might distinguish this case from other -- I don't know,
24 but in this case, it's -- there's no issue on the concerns your
25 Honor was raising.

1 THE COURT: Okay.

2 MR. VAN: Okay. So they say, well, in August 2016
3 there was this letter from the FDA, and that must have given
4 them some strain of hope. So it was fine for them to lie about
5 their progress. No. The August 2016 letter was just a
6 statement that the remediation plan that the company had given
7 looked good to the FDA. It was in no sense some kind of an
8 affirmation from the FDA that the problems had actually been
9 resolved. It didn't even speak to whether the problems had
10 been resolved. So there's certainly no reasonable reliance
11 that defendants had on this letter saying the plan -- you know,
12 if you were to do all these things, then, you know, you'd be
13 looking good for approval. And we believe that they didn't do
14 anything, that they didn't follow up what they intended to do
15 in the August 2016 letter. So it's of no value to a defendant.

16 The March 2017 misstatements. Okay. So this is,
17 again, just a statement of cGMP compliance. It's false and
18 misleading for the reasons we've described. There are these
19 two fundamental, you know, red siren issues that this company
20 had not dealt with, you know, within -- six weeks later when
21 there was an inspection and those problems weren't resolved.
22 And everybody should have known that. Everybody in this room,
23 certainly defendant Ankerud, should have known that these
24 problems put them nowhere near cGMP compliance.

25 Then they say, okay, well, there are these disclosures

1 that we had in our Form 10-K, and those disclosures were --
2 there were issues with the, quote, manufacturing processes,
3 issues with, quote, analytical testing and a particulate matter
4 issue. So it's actually verifiable -- like this is an unusual
5 case in which we can actually verify the significance of what
6 was omitted from these statements, just how little these
7 statements told investors, and that's because -- defendants are
8 correct -- defendants revealed they'd received a Form 483 and
9 said these three cute phrases about the Form 483.

10 But then -- then -- in July of 2017, when for the
11 first time Seeking Alpha, a Wall Street reporter, actually made
12 public the actual Forms 483, and the public investors learned
13 for the first time all the detail that was in those Form 483s,
14 importantly learned for the first time the big, you know,
15 blaring red sirens that should have been articulated about what
16 was in the Forms 483, when investors learned what was -- you
17 know, that the stock tanked 30 percent. There's simply no
18 question that what was left out mattered a whole lot. They
19 didn't convey what they needed to.

20 Okay. The May 5 comments follows the last set of
21 statements and some of the most outrageous. The company said
22 one day after receiving this Form 483 detailing the conditions
23 of the factory, the manufacturing operations as they were,
24 showing that almost half of their product that they released to
25 the public contained particulate matter inclusive of heavy

1 metals. One day later the company says, "Our manufacturing
2 process is in a fully developed mode." Not once, twice on the
3 conference call they said, "Fully developed." "Our
4 manufacturing process is fully developed." Nothing more to be
5 done. Capital F fraud.

6 The other statements on the May 5 conference call I
7 don't like as much. The second one I like more than the third.
8 The second one is -- in response to a question, "Is there
9 anything that could delay the action dates specifically," and
10 Ankerud replied, "Nothing that we can currently see. Nothing
11 could delay -- nothing that we can currently see could delay
12 the PDUFA action date." That's not a statement about the
13 future. It's actually a statement of current conditions,
14 current potential. The conditions as they are, nothing among
15 those current conditions that we can see could delay the PDUFA
16 date. It's just an outrageous statement. It's verifiably
17 wrong given the conditions in the factory as described and
18 alleged one day prior.

19 The third is a forward-looking statement, frankly,
20 that they couldn't resolve -- or that the company could resolve
21 the problems in a timely manner, as in the next six weeks or
22 so. That was flatly wrong, but it's nevertheless actionable,
23 because there was an omission in that statement. Even if they
24 absurdly believed that within six months they could turn around
25 these massive problems, they omitted the facts that all the

1 other investors and the rest of the rational world wanted to
2 know, that there are these huge red flags, problems in the
3 company. And statements of omission are actionable. The safe
4 harbor provision does not apply to them.

5 So I think we've already discussed scienter direct,
6 and the argument is pretty simple. If you don't have a recipe,
7 if you don't know how to make your product and you have stuff
8 floating around in your product you haven't identified, there's
9 just no way that you're compliant with any reasonable
10 regulations. You don't even have to know what the regulations
11 are. If you know that much about your company, you know you're
12 not going to be compliant.

13 But there's a cherry on top of the scienter cake, and
14 that's a confidential witness who was there and who spoke with
15 defendant Ankerud. And we've described this person in
16 sufficient detail. All we have to allege is enough to make
17 probable that this person was in a position to have had a
18 conversation with Ankerud, and that's clear. He was in
19 regulatory affairs. He worked two levels away from Ankerud.
20 This is a 94-person company. Regulatory affairs couldn't have
21 had more than ten, five people. So certainly it's probable
22 that he was in a position to have a conversation with Ankerud,
23 and that conversation, which was in January 2017, was one in
24 which Ankerud said, "We know that these batch records that
25 we're submitting to the FDA don't resolve the problems that

1 were identified by the FDA that they are not FDA compliant."

2 Now, I have to admit that the complaint on the
3 confidential witness could have been clearer, and I think that
4 a lot of the disputes that defendants had with the confidential
5 witness here are disputes about that clarity. I can represent
6 to the court that it's clear to us, at least, that the
7 confidential witness was talking about compliance with cGMP and
8 the company's failure as of that date to be compliant with
9 cGMP. But even if the court doesn't want to accept our
10 representations now, there's plenty for scienter, even if we
11 completely ignore the confidential witness and the confidential
12 witness is nevertheless a cherry on top of the scienter cake,
13 because it shows that the defendants were perfectly willing to
14 submit records to the FDA that they knew would not be
15 compliant.

16 THE COURT: Does that pertain only to the 2017
17 allegations?

18 MR. VAN: So if falsity were actually an issue in this
19 case with respect to any of this, which it is not, then it
20 would buttress falsity with respect to the March 2017
21 conclusions. As for scienter, it buttresses all of the
22 scienter allegations because it's clear that the defendants
23 were perfectly willing to submit records to the FDA that
24 weren't compliant. They were willing to be non-compliant with
25 FDA regulations. And that is absolutely a part of the holistic

1 picture that the court must consider under *Tellabs* in its
2 scienter analysis.

3 I think that covers it, your Honor. I'd love to
4 answer any questions or concerns that you have.

5 THE COURT: All right. I've asked them. Thanks.

6 MR. VAN: Okay.

7 MR. BONGIORNO: May I briefly, your Honor?

8 THE COURT: Briefly.

9 MR. BONGIORNO: Thank you.

10 I'll start where Mr. Van ended, with the confidential
11 witness. I've done a lot of these arguments over the years.
12 It's the first time I've heard that oral argument, a
13 confidential witness statement be amended to basically say that
14 the defendant committed fraud or whatever he just quoted, which
15 is nowhere in the complaint.

16 Mr. Van just said something like the confidential
17 witness said or heard Mr. Ankerud say, "We know" -- and then he
18 repeated the word "know" loudly -- "that what we're submitting
19 doesn't resolve the problems identified by the FDA." That's a
20 very convenient statement. I suspect that if the confidential
21 witness had reported that to the private investigator, who then
22 reported that to somebody at one of these firms, who then put
23 it in the complaint, it would have made it into the complaint.
24 It's very hard for me to believe that lawyers as good as
25 Pomerantz would forget to put in the complaint a statement that

1 says, "We know that we didn't resolve issues." That's not what
2 the complaint says.

3 If that's what they want to allege, and I've said this
4 before in other courtrooms in this building, if that's what
5 they want to allege, put it in the complaint and let's attack
6 it. Don't show up at oral argument and tell us what the
7 confidential witness would have said or did say but didn't make
8 it into the complaint. It's not fair.

9 It's not fair that Mr. Ankerud, who is a named
10 defendant in this case, is accused of fraud. It's also not
11 fair to the two other individuals who were accused of fraud and
12 named in the complaint and then dropped in the opposition to
13 the motion to dismiss. If you're going to accuse somebody of
14 fraud, accuse them of fraud. It's very unfortunate to hear
15 that today.

16 In any event, I want to be clear on a couple of other
17 things. The particulate matter that was found or suspected to
18 be found in this product was in 2017, not 2016. And I want to
19 correct something else important. It was not, as plaintiffs'
20 counsel just said, released to the public. The product was not
21 being sold at that time. Nobody got product that had
22 particulate matter in it.

23 In *Genzyme*, however, because he said I'm not sure what
24 the other cases say on this point, we can be sure because in
25 *Genzyme*, the First Circuit says, "Genzyme and the FDA issued a

1 public notice to health care providers explaining that vials of
2 Cerezyme, Fabrazyme, and Myozyme were discovered to have been
3 contaminated with foreign particles, such as steel and
4 non-latex rubber."

5 Okay. And by the way, the FDA and Genzyme entered
6 into a consent decree requiring Genzyme to pay \$175 million in
7 fines. This is Genzyme that said they were confident that the
8 product produced at the Allston facility continued to meet the
9 highest quality and safety standards. And that case was
10 dismissed and that dismissal was affirmed.

11 So that's what we have in that case. What do we have
12 in this case? We have a 483 that was disclosed that either may
13 or may not establish a basis for falsity, depending on which
14 part of the brief you want to believe, which part of the
15 argument you want to believe today, because we heard the entire
16 spectrum from it establishes everything that's in it to it
17 establishes every fact to it establishes a violation of cGMP,
18 and I don't know which theory to attack because I heard all of
19 them today. But the bottom line is that that's all it is, is a
20 483. It's not something to be taken lightly. It's not
21 something to be ignored. It is important. But it is, as the
22 court recognized in *Genzyme*, and I think perhaps suggested in
23 some of the questions today, that it's at least an issue in
24 this case, and I agree it is, if that's the court's
25 inclination.

1 The prefatory language in the 483 basically says if
2 you want to talk about this, if you have any objection to it,
3 if you want to respond to it, here's how you do it. You may
4 discuss the objection or action with the FDA representative
5 during the inspection or submit information to the FDA at the
6 address above. If you have any questions, call us. And his
7 response to that is that's not what happened here. That is
8 what happened here. That is exactly what happened here.

9 And this notion that we didn't have a recipe, which
10 must have been said 40 times in this courtroom this afternoon,
11 of course there was a recipe. I think a recipe is what are the
12 ingredients that go into the drug. I think that's what it must
13 mean.

14 There was no issue about efficacy. There was no issue
15 about safety. The issue here was a manufacturing issue.
16 Nobody said, "Your drug doesn't work. Go back and make it
17 work, or you're not going to get approved." It was all issues
18 that we've been talking about all afternoon with the
19 manufacturing process that were ultimately fortunately
20 resolved.

21 So did the company have a recipe? Of course it did.
22 Did the company need to overcome some observations that the FDA
23 made? Yes. And were they able to do in it a timely manner?
24 Not as quickly as they'd like but they ultimately did. And
25 that's what this case is about and that's why this case is an

1 easier case to dismiss than many of the other cases that we've
2 cited and some of the other cases in this court, all of which
3 have been dismissed. And that's why I ask that this court
4 dismiss this case. Thank you.

5 THE COURT: Thank you. I'll take the matter under
6 advisement.

7 THE CLERK: All rise for the court.

8 (12:57 p.m.)
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C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS)

I certify that the foregoing is a correct transcript
from the record of proceedings taken February 6, 2019 in the
above-entitled matter to the best of my skill and ability.

/s/ Kathleen Mullen Silva

2-28-19

Kathleen Mullen Silva, RPR, CRR
Official Court Reporter

Date